I. Background

All medical devices have benefits and risks. Health care providers, patients, and consumers must weigh these benefits and risks when making health care decisions. FDA weighs probable benefit to health from the use of the device against any probable risk of injury or illness from such use in determining the safety and effectiveness of a device. However, not all information regarding benefits and risks for a given device may be fully known or characterized prior to the device reaching the market. New information about the safety and/or effectiveness of the device often becomes available once the device is more widely distributed and used under real-world conditions of actual clinical practice.

FDA is issuing this draft guidance to describe the Agency's policy for notifying the public about medical device ''emerging signals.'' For the purposes of this guidance, an emerging signal is new information about a medical device used in clinical practice: (1) That the Agency is monitoring or analyzing, (2) that has the potential to impact patient management decisions and/or alter the known benefit-risk profile of the device, (3) that has not yet been fully validated or confirmed, and (4) for which the Agency does not yet have specific recommendations.

We believe there is a need to notify the public about emerging signals that the Agency is monitoring or analyzing, even when the information has not been fully analyzed, validated, or confirmed, and for which the Agency does not yet have specific recommendations. Timely communication about emerging signals is intended to provide health care providers, patients, and consumers with access to the most current information concerning the potential benefits and risks of marketed devices, so that they can make informed treatment choices bases on all available information. Therefore, because of the evolving nature of this information, FDA would be sharing it with the public at an early stage of the Agency's assessment and evaluation of the signal.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Public Notification of Emerging Postmarket Medical Device Signals ('Emerging Signals').'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.regulations.gov.* Persons unable to download an electronic copy of ''Public Notification of Emerging Postmarket Medical Device Signals ('Emerging Signals')'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1500027 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR parts 801 and 808, regarding labelling, have been approved under OMB control number 0910–0485 and the collections of information in 21 CFR part 803, regarding medical device reporting, have been approved under OMB control numbers 0910–0291, 0910–0437, and 0910–0471.

Dated: December 28, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–32920 Filed 12–30–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60 Day Comment Request; The Framingham Heart Study (NHLBI)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH), will publish periodic summaries of proposed projects to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Paul Sorlie, 6701 Rockledge Drive, MSC 7936, Bethesda, MD 20892, or call non-toll-free number (301) 435–0456, or Email your request to: *sorliep@nhlbi.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Proposed Collection: The Framingham Heart Study, Revision, 0925–0216 Expiration Date: 10/31/2016, National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH).

Need and Use of Information Collection: This proposal is to extend the Framingham Study to examine the Generation Three Cohort, New Offspring Spouses and Omni Group 2 Cohort, as well as to continue to monitor the morbidity and mortality which occurs in all Framingham Cohorts. The contractor, with the collaborative assistance of NHLBI Intramural staff, will invite study participants, schedule appointments, administer examinations and testing, enter information into computer databases for editing, and prepare scientific reports of the information for publication in appropriate scientific journals. All

participants have been examined previously and thus the study deals with a stable, carefully described group. Data are collected in the form of an observational health examination involving such components as blood pressure measurements, venipuncture, electrocardiography and a health interview, including questions about lifestyles and daily living situations. The National Heart, Lung, and Blood Institute uses the results of the Framingham Study to: (1) Characterize risk factors for cardiovascular and lung diseases so that national prevention programs can be designed and implemented; (2) evaluate trends in cardiovascular diseases and risk factors over time to measure the impact of overall preventive measures; and (3) understand the etiology of cardiovascular and lung diseases so that effective treatment and preventive modalities can be developed and tested. Most of the reports of study results have been published in peer reviewed medical journals and books.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 8,382.

Estimated Annualized Burden Hours

TABLE A.12–1.1—ESTIMATE OF RESPONDENT BURDEN, ORIGINAL COHORT

[Annualized]

Type of respondent	Number of respondents	Number of responses per respondent	Average time per response (in hours)	Total annual burden hour
I. PARTICIPANT COMPONENTS				
ANNUAL FOLLOW-UP				
a. Records Request	30	1	15/60	8
b. Health Status Update	30	1	15/60	8
SUB–TOTAL: PARTICIPANT COMPONENTS	*30			15
II. NON-PARTICIPANT COMPONENTS				
A. Informant Contact (Pre-exam and Annual Follow-up)	15	1	10/60	3
B. Records Request (Annual follow-up)	30	1	15/60	8
SUB-TOTAL: NON-PARTICIPANT COMPONENTS	45			10
TOTAL: PARTICIPANT AND NON-PARTICIPANT COMPONENTS	75			25

*Number of participants as reflected in Row I.b. above.

TABLE A.12–1.2—ESTIMATE OF RESPONDENT BURDEN, OFFSPRING COHORT AND OMNI GROUP 1 COHORT

[Annualized]

Type of respondent	Number of respondents	Number of responses per respondent	Average time per response (in hours)	Total annual burden hour
I. PARTICIPANT COMPONENTS				
ANNUAL FOLLOW-UP				
a. Records Request	1,500	1	15/60	375
b. Health Status Update	1,700	1	15/60	425
SUB-TOTAL: PARTICIPANT COMPONENTS	*1,700			800
II. NON-PARTICIPANT COMPONENTS				
A. Informant contact (Pre-exam and Annual Follow-up)	150	1	10/60	25
B. Records Request (Annual follow-up)	1,500	1	15/60	375
SUB-TOTAL: NON-PARTICIPANT COMPONENTS	1,650			400
TOTAL: PARTICIPANT AND NON-PARTICIPANT COMPONENTS	3,350			1,200

*Number of participants as reflected in Row I.b. above.

TABLE A.12–1.3—ESTIMATE OF RESPONDENT BURDEN, GENERATION 3 COHORT, NOS AND OMNI GROUP 2 COHORT

[Annualized]

Type of respondent	Number of respondents	Number of responses per respondent	Average time per response (hours per year)	Total annual burden hour
I. PARTICIPANT COMPONENTS				
A. PRE-EXAM:				
1.Telephone contact for appointment	1,450	1	10/60	242
2. Exam appointment, scheduling, reminder and instructions	1,270	1	35/60	741
B. EXAM CYCLE 3:				
1. Exam at study center	1,200	1	110/60	2,200

TABLE A.12–1.3—ESTIMATE OF RESPONDENT BURDEN, GENERATION 3 COHORT, NOS AND OMNI GROUP 2 COHORT—Continued

[Annualized]

Type of respondent	Number of respondents	Number of responses per respondent	Average time per response (hours per year)	Total annual burden hour
2. Home or nursing home visit	35	1	60/60	35
C. POST-EXAM:				
eFHS Mobile Technology for Collection of CVD Risks	1,100	18	9/60	2,970
D. ANNUAL FOLLOW-UP:				
1. Records Request	1,200	1	15/60	300
2. Health Status Update	1,400	1	15/60	350
Sub-Total: Participant Components	*2,850			6,830
II. NON-PARTICIPANT COMPONENTS—ANNUAL FOLLOW-UP				
A. INFORMANT CONTACTS	180	1	10/60	30
B. RECORD REQUEST	1,155	1	15/60	289
Sub-Total: Non-Participant Components	1,335			319
Total: Participant And Non-Participant Components	4,185			7,157

*Number of participants as reflected in Rows I.A.1 and I.D.2 above.

Dated: December 22, 2015.

Valery Gheen,

NHLBI Project Clearance Liaison, National Institutes of Health.

[FR Doc. 2015–32940 Filed 12–30–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Board of Scientific Counselors, NIDA.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Institute on Drug Abuse, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, NIDA.

Date: February 1–2, 2016.

Closed: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: Intramural Research Program, National Institute on Drug Abuse, NIH, Johns Hopkins Bayview Campus, Baltimore, MD 21223.

Contact Person: Joshua Kysiak, Program Specialist, Biomedical Research Center, Intramural Research Program, National Institute on Drug Abuse, NIH, DHHS, 251 Bayview Boulevard, Baltimore, MD 21224, 443–740–2465, *kysiakjo@nida.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos.: 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: December 28, 2015.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–32939 Filed 12–30–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable materials, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; Tools for Monitoring and Manipulating RNA Modifications (R41, R42, R43, R44).

Date: February 18, 2016.

Time: 9:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Garden Inn Bethesda, 7301 Waverly Street, Bethesda, MD 20814.

Contact Person: Jagadeesh S. Rao, Ph.D., Scientific Review Officer, Office of Extramural Policy and Review, National Institute on Drug Abuse, National Institutes of Health, DHHS, 6001 Executive Boulevard, Room 4234, MSC 9550, Bethesda, MD 02892, 301–443–9511, *jrao@nida.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos.: 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: December 28, 2015.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–32937 Filed 12–30–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as